

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
NORTHERN DIVISION**

ELIZABETH WOHLBERG,
3228 MIDFIELD ROAD
PIKESVILLE, MD 21208
[Baltimore County, MD]

COMPLAINT AND JURY DEMAND

No. _____

V.

ETHICON, INC.
ROUTE 22 WEST
SOMERVILLE, NJ 08876
[Somerset County, NJ]

and

**JOHNSON & JOHNSON,
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933
[Middlesex County, NJ]**

Defendants.

CIVIL ACTION COMPLAINT

Plaintiff, ELIZABETH WOHLBERG (“Plaintiff”), by and through her counsel, brings this Complaint to set forth against Defendants’ ETHICON, INC., and JOHNSON & JOHNSON (collectively, “Defendants”, as the context may require) for injuries suffered as a result of the implantation of defective pelvic mesh products designed, manufactured and marketed by Defendants’. In support, Plaintiff states and avers as follows:

PARTIES

1. Plaintiff Elizabeth Wohlberg, is, and was, at all relevant times, a citizen and resident of the state of Maryland, county of Baltimore.

2. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

3. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson and is incorporated in the state of New Jersey with its principal place of business in Somerville, New Jersey.

4. Defendants ETHICON, INC. and JOHNSON & JOHNSON share many of the same officers, directors and operations; and maintain ownership in the assets and/or liabilities relating to the design, manufacture, marketing, distribution and sale of the medical device line at issue in this litigation and shall be referenced collectively hereinafter as "Defendants".

5. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

JURISDICTION AND VENUE

6. Damages sought in this matter are in excess of \$75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

7. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

8. Venue on remand is proper in the District Court of Maryland pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in this district.

9. Defendants conducted substantial business in the State of Maryland and in this District, distribute Pelvic Mesh Products in this District, receive substantial compensation and profits from sales of Pelvic Mesh Products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to

subject them to *in personam* jurisdiction in this District.

10. Defendants conducted business in the State of Maryland through sales representatives conducting business in the State of Maryland and because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and/or selling, either directly or indirectly, and/or through third parties or related entities, Pelvic Mesh Products; thus, there exists a sufficient nexus between Defendant forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in Maryland.

11. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants are present in the State of Maryland such that requiring an appearance does not offend traditional notices of fair play and substantial justice.

DEFENDANTS' PELVIC MESH PRODUCTS

12. In or about October 2002, the Defendants began to market and sell a product known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Gynemesh include all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.

13. Gynemesh was derived from a product known as Prolene Mesh, which was used in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants' prolene mesh hernia product, and was and is utilized in the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All references to Prolene Mesh include all variations of Prolene Mesh, including but not limited to Prolene Soft Mesh.

14. In or about September 2005, the Defendants began to market and sell a

1 product known as Prolift, for the treatment of medical conditions in the female pelvis,
2 primarily pelvic organ prolapse and stress urinary incontinence. The Prolift was and is offered
3 as an anterior, posterior, or total repair system, and all references to the Prolift include by
4 reference all variations.
5

6 15. In or about May 2008, the Defendants began to market and sell a product
7 known as Prolift+M, for the treatment of medical conditions in the female pelvis, primarily
8 pelvic organ prolapse and stress urinary incontinence. The Prolift+M was and is offered as an
9 anterior, posterior, or total repair system, and all references to the Prolift+M include by
10 reference all variations.
11

12 16. The Defendants market and sell a product known as TVT, for the treatment of
13 stress urinary incontinence in females. The TVT has been and is offered in multiple variations
14 including, but not limited to, the TVT, TVT-O, and TVT-S, and all references to the TVT
15 include by reference all variations.
16

17 17. The products known as Prolene Mesh, Gynemesh, Prolift, Prolift+M, and
18 TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar
19 purposes, inclusive of the instruments and procedures for implantation, are collectively
20 referenced herein as Defendants' Pelvic Mesh Products or the Pelvic Mesh Products.
21

22 18. Defendants' Pelvic Mesh Products were designed, patented, manufactured,
23 labeled, marketed, and sold and distributed by the Defendants, at all times relevant herein.
24

FACTUAL BACKGROUND

25 19. On December 19, 2013, Plaintiff was implanted with an Ethicon/Johnson &
26 Johnson Gynecare TVT-O ("Pelvic Mesh Products", "Pelvic Mesh Product", and/or
27 "Product") during surgery performed at Greater Baltimore Medical Center in Towson,
28 Maryland.

1 20. The Pelvic Mesh Product was implanted in Plaintiff to treat her stress urinary
2 incontinence, the use for which the Pelvic Mesh Product was designed, marketed and sold.

3 21. On August 30, 2017, Plaintiff underwent a revision surgery of the
4 Ethicon/Johnson & Johnson TVT-O product at Sinai Hospital in Baltimore, Maryland. The
5 revision surgery was necessary because the TVT-O product implanted in Plaintiff had become
6 inflamed causing Plaintiff to suffer from chronic pain with daily activities and dyspareunia.
7

8 22. As a result of having the Product implanted in her, Plaintiff has experienced
9 significant mental and physical pain and suffering, has sustained permanent injury and
10 permanent and substantial physical deformity and has suffered financial or economic loss,
11 including, but not limited to, obligations for medical services and expenses.

13 23. Defendants' Pelvic Mesh Product has been and continues to be marketed to
14 the medical community and to patients as a safe, effective, reliable, medical device; implanted
15 by safe and effective, minimally invasive surgical techniques for the treatment of medical
16 conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and
17 more effective as compared to the traditional products and procedures for treatment, and other
18 competing pelvic mesh products.

20 24. The Defendants have marketed and sold the Defendants' Pelvic Mesh Product
21 to the medical community at large and patients through carefully planned, multifaceted
22 marketing campaigns and strategies. These campaigns and strategies include, but are not
23 limited to direct to consumer advertising, aggressive marketing to health care providers at
24 medical conferences, hospitals, private offices, and include the provision of valuable
25 consideration and benefits to health care providers. Also utilized are documents, brochures,
26 websites, and telephone information lines, offering exaggerated and misleading expectations
27 as to the safety and utility of the Defendants' Pelvic Mesh Product.
28

1 25. Contrary to the Defendants' representations and marketing to the medical
2 community and to the patients themselves, the Defendants' Pelvic Mesh Product has high
3 failure, injury, and complication rates, fails to perform as intended, requires frequent and often
4 debilitating re-operations, and has caused severe and irreversible injuries, conditions, and
5 damage to a significant number of women, including the Plaintiff.
6

7 26. The Defendants have consistently underreported and withheld information
8 about the propensity of Defendants' Pelvic Mesh Product to fail and cause injury and
9 complications, and have misrepresented the efficacy and safety of the Product, through
10 various means and media, actively and intentionally misleading the FDA, the medical
11 community, patients, and the public at large.
12

13 27. Defendants have known and continue to know that their disclosures to the
14 FDA were and are incomplete and misleading; and that the Defendants' Pelvic Mesh Product
15 was and is causing numerous patients' severe injuries and complications. The Defendants
16 suppressed this information and failed to accurately and completely disseminate or share this
17 and other critical information with the FDA, health care providers, or the patients. As a result,
18 the Defendants actively and intentionally misled and continue to mislead the public, including
19 the medical community, health care providers and patients, into believing that the Defendants'
20 Pelvic Mesh Product was and is safe and effective, leading to the prescription for and
21 implantation of the Pelvic Mesh Product into the Plaintiff.
22
23

24 28. Defendants failed to perform or rely on proper and adequate testing and
25 research in order to determine and evaluate the risks and benefits of the Defendants' Pelvic
26 Mesh Product.
27

28 29. Defendants failed to design and establish a safe, effective procedure for
removal of the Defendants' Pelvic Mesh Product; therefore, in the event of a failure, injury, or

1 complications it is impossible to easily and safely remove the Defendants' Pelvic Mesh
2 Product.

3 30. Feasible and suitable alternative designs as well as suitable alternative
4 procedures and instruments for implantation and treatment of stress urinary incontinence,
5 pelvic organ prolapse, and similar other conditions have existed at all times relevant as
6 compared to the Defendants' Pelvic Mesh Product.

7 31. The Defendants' Pelvic Mesh Product was at all times utilized and implanted
8 in a manner foreseeable to the Defendants.

9 32. The Defendants have at all times provided incomplete, insufficient, and
10 misleading training and information to physicians, in order to increase the number of
11 physicians utilizing the Defendants' Pelvic Mesh Product, and thus increase the sales of the
12 Product, and also leading to the dissemination of inadequate and misleading information to
13 patients, including Plaintiff.

14 33. The Pelvic Mesh Product implanted into the Plaintiff was in the same or
15 substantially similar condition as it was when it left the possession of Defendants, and in the
16 condition directed by and expected by the Defendants.

17 34. The injuries, conditions, and complications suffered due to Defendants'
18 Pelvic Mesh Product include but are not limited to mesh erosion, mesh contraction, infection,
19 fistula, inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and
20 other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage,
21 pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women
22 have been forced to undergo intensive medical treatment, including but not limited to
23 operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue,
24 and nerve damage, the use of pain control and other medications, injections into various areas
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27
28

of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia, and injuries to Plaintiff's intimate partners.

35. Despite Defendants' knowledge of these catastrophic injuries, conditions, and complications caused by their Pelvic Mesh Product, the Defendants have, and continue to manufacture, market, and sell the Product, while continuing to fail to adequately warn, label, instruct, and disseminate information with regard to the Defendants' Pelvic Mesh Product, both prior to and after the marketing and sale of the Product.

COUNT I

36. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

37. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the proper candidates, and the safest and most effective methods of implantation and use of the Defendants' Pelvic Mesh Product.

38. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers as to the risks and benefits of the Defendants' Pelvic Mesh Product, given the Plaintiff's conditions and need for information

39. The Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the Pelvic Mesh Product, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Product.

40. In addition, the Products were defective due to the lack of necessary and appropriate warnings regarding, but not limited to, the following:

- a) the Products' propensities to contract, retract, and/or shrink inside the body;
 - b) the Products' propensities for degradation, fragmentation, disintegration

1 and/or creep;

- 2 c) That the Defendants' device was defective, and caused dangerous and
3 adverse side effects, including but not limited to higher incidence of erosions,
4 extrusions, adverse tissue response and rejection, contraction, migration,
5 trauma, groin pain, vaginal pain, failure, and revision surgeries at a much
6 more significant rate than other products, treatments and procedures
7 available to treat pelvic organ prolapse;
- 8 d) That patients needed to be monitored more regularly than usual while using
9 the Defendants' device and that in the event the product needed to be
attempted to revise or be removed that the procedures to remove segments of
the product had a very high failure rate and/or needed to be performed
repeatedly;
- 10 e) the Products' inelasticity preventing proper mating with the pelvic floor and
11 vaginal region;
- 12 f) the rate and manner of mesh erosion or extrusion;
- 13 g) the risk of chronic inflammation resulting from the Products;
- 14 h) the risk of chronic infections resulting from the Products;
- 15 i) the risk of permanent vaginal or pelvic scarring as a result of the Products;
- 16 j) the risk of recurrent, intractable pelvic pain and other pain resulting from the
17 Products;
- 18 k) the need for corrective or revision surgery to adjust or remove the Products;
- 19 l) the severity of complications that could arise as a result of implantation of
20 the Products
- 21 m) the hazards associated with the Products;
- 22 n) the Products' defects described herein
- 23 o) treatment of pelvic organ prolapse and stress urinary incontinence with the
24 Products is no more effective than feasible available alternatives;
- 25 p) treatment of pelvic organ prolapse and stress urinary incontinence with the
26 Products exposes patients to greater risk than feasible available alternatives;
- 27 q) treatment of pelvic organ prolapse and stress urinary incontinence with the
28 Products makes future surgical repair more difficult than feasible available
alternatives;

- i) use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;
 - s) removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and
 - t) complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

41. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of the Defendants' Pelvic Mesh Product, understating the risks and exaggerating the benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

42. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Product, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

43. The Defendants are strictly liable in tort to the Plaintiff for their wrongful conduct.

WHEREFORE, Plaintiffs demand judgment against Defendants of compensatory damages, punitive damages, interest, attorneys' fees, costs of suit, and such further relief as the Court deems equitable and just.

COUNT II

44. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

45. At the time of Plaintiff's injuries, the Defendants' Pelvic Mesh Product was defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiff, and the warnings labels and instructions were deficient.

46. The Ethicon TVT-O product was placed into the stream of commerce by the

1 Defendants with the expectation that it would reach consumers in Maryland without
2 substantial change in condition and, as of December 19, 2013, there had been no substantial
3 change in the condition of the TVT-O device.
4

5 47. The TVT-O product implanted in ELIZABETH WOHLBERG was in the
6 same or substantially similar condition as when it left the Defendants' possession, and in the
7 condition directed by and expected by the Defendants.

8 48. The Product implanted in the Plaintiff was not reasonably safe for its
9 intended use and was defective with respect to its manufacture, as described herein, in that
10 Defendants deviated materially from their design and manufacturing specifications and/or
11 such design and manufacture posed an unreasonable risk of harm to patients in whom the
12 Products were implanted.

14 49. The Products are inherently dangerous and defective, unfit and unsafe for
15 their intended and reasonably foreseeable uses, and do not meet or perform to the
16 expectations of patients and their health care providers.
17

18 50. The Products create risks to the health and safety of the patients that are far
19 more significant and devastating than the risks posed by other products and procedures
20 available to treat the corresponding medical conditions, and which far outweigh the utility
21 of the Products.
22

23 51. The Defendants have intentionally and recklessly manufactured, the
24 Products with wanton and willful disregard for the rights and health of the Plaintiff and
25 others, and with malice, placing their economic interests above the health and safety of the
26 Plaintiff and others.
27

28 52. The Product implanted in the Plaintiff was not reasonably safe for its
intended use and was defective as described herein with respect to its design. As previously

1 stated, the Products' design defects include, but are not limited to:

- 2 a) the use of polypropylene material and/or collagen material in the Products
3 and the immune reaction that results from such material, causing adverse
4 reactions and injuries;
- 5 b) the design of the Products to be inserted into and through an area of the body
6 with high levels of bacteria that adhere to the mesh causing immune
7 reactions and subsequent tissue breakdown and adverse reactions and
injuries;
- 8 c) biomechanical issues with the design of the Products, including, but not
9 limited to, the propensity of the Products to contract or shrink inside the
body, that in turn cause surrounding tissue to be inflamed, become fibrotic,
and contract, resulting in injury;
- 10 d) the use and design of arms and anchors in the Products, which, when placed
11 in the women, are likely to pass through contaminated spaces and injure
12 major nerve routes in the pelvic region;
- 13 e) the propensity of the Products for "creep," or to gradually elongate and
deform when subject to prolonged tension inside the body;
- 14 f) the inelasticity of the Products, causing them to be improperly mated to the
15 delicate and sensitive areas of the pelvis where they are implanted, and
16 causing pain upon normal daily activities that involve movement in the
17 pelvis (e.g., intercourse, defecation);
- 18 g) the propensity of the Products for degradation or fragmentation over time,
19 which causes a chronic inflammatory and fibrotic reaction, and results in
continuing injury over time;
- 20 h) the propensity of the Products for particle loss or "shedding", which causes a
21 chronic inflammatory response and fibrotic reaction, and results in
22 continuing injury over time; the lack of porosity of the Products, which leads
to fibrotic bridging and results in continuing injury over time; and
- 23 i) the creation of a non-anatomic condition in the pelvis leading to chronic pain
24 and functional disabilities when the mesh is implanting according to the
manufacturers' instructions.

25
26 53. Plaintiff adopts the Plaintiff adopts the *Restatement of Torts (Second)* and/or
27 the *Restatement of Torts (Third)*, bringing strict product liability claims under the common
28 law, *Section 402A of the Restatement of Torts (Second)*, and/or *Restatement of Torts*

(*Third*) against Defendants.

54. As a proximate result of the Defendants' design, manufacture, marketing, sale, and distribution of the Pelvic Mesh Product, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

55. Specifically, the TVT-O implanted in ELIZABETH WOHLBERG became inflamed causing Plaintiff to suffer from severe complications, including but not limited to: chronic pelvic pain, dyspareunia, and economic damages.

56. The Defendants failed to exercise ordinary care in the representations concerning the Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because the Defendants negligently misrepresented the Products' high risk of unreasonable, dangerous, adverse side effects.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III
NEGLIGENCE

57. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

58. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, and distribution of the Defendants' Pelvic Mesh Product, and recruitment and training of physicians to implant the Pelvic Mesh Product.

1 59. Defendants breached their duty of care to the Plaintiff, as aforesaid, in the
2 manufacture, design, labeling, warnings, instructions, sale, marketing, distribution, and
3 recruitment and training of physicians to implant the Pelvic Mesh Product.
4

5 60. At all times material, Defendants failed to exercise reasonable care under the
6 circumstances, as it knew, or in the exercise of reasonable care, should have known, that its
7 Pelvic Mesh Product was not properly manufactured, compounded, assembled, inspected,
8 packaged, distributed, tested, analyzed, examined, or prepared, such that the medical device
9 was defective, unreasonably dangerous, and likely to injure its users, including Plaintiff
10 herein.
11

12 61. Also, Defendants failed to exercise reasonable care under the circumstances,
13 as it knew, or in the exercise of reasonable care, should have known, that its Pelvic Mesh
14 Products were sold without sufficient warnings or instruction (both before as well as after
15 their sale), such that the Gynecare Prolift mesh device was likely to injure its users,
16 including Plaintiff herein.
17

18 62. As a result of said failures, the TVT-O brand mesh device implanted in
19 Plaintiff was unreasonably dangerous and defective in design and unaccompanied by
20 adequate warnings concerning its hazardous properties.
21

22 63. Further, Defendants failed to exercise reasonable care under the
23 circumstances, as it knew, or in the exercise of reasonable care, should have known, that its
24 Pelvic Mesh Products and the information (including warnings, instructions, detailing,
25 advertising, promotion, and representations) about the characteristics and properties of the
26 device; the potential risks associated with its use in patients; safety and efficacy data; the
27 attributes of the device relative to other competing medical devices; and the management of
28 patients after implantation of this device were inaccurate or incomplete, such that the

1 medical device was likely to injure its users, including Plaintiff herein.

2 64. Defendants also failed to conduct sufficient testing, quality assurance
3 measures and/or inspection of its Pelvic Mesh Product, both prior to and after clearance of
4 the product for sale, which, if properly performed, would have revealed or led, long ago, to
5 the detection of defects in the Pelvic Mesh Product and inadequacy in the warnings,
6 promotional materials and instructions which accompanied the device, such that the injuries
7 suffered by Plaintiff herein could have been prevented.
8

9 65. These negligent acts by Defendants resulted in the sale of Pelvic Mesh
10 Products that were unreasonably dangerous, unsafe, and not reasonably fit for the uses and
11 purposes for which the medical device would ordinarily be put or some other reasonably
12 foreseeable purpose and the unreasonably dangerous condition existed when such device,
13 including the particular device implanted in Plaintiff, left Defendants' custody and control.
14

15 66. Defendants knew or should have known that the Pelvic Mesh Product
16 subjected Plaintiff to unreasonably dangerous risks of which the Plaintiff and her treating
17 physicians would not be aware. Nevertheless, Defendants advertised, marketed, sold and
18 distributed the Pelvic Mesh Product device for years to thousands of women, at a time when
19 Defendants knew that there were safer methods and products available for the treatment of
20 pelvic organ prolapse.
21

22 67. Had Plaintiff, her treating physician, or both known of the unreasonably
23 dangerous risks associated with the TVT-O product at the time of her implant surgery, such
24 knowledge would have affected the treating physician's use of the device and Plaintiff
25 would not have consented to the implantation of the device.
26

27 68. As a proximate result of the Defendants' design, manufacture, labeling,
28 marketing, sale, and distribution of the Pelvic Mesh Product, Plaintiff has been injured, often

catastrophically, sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV
NEGLIGENT MISREPRESENTATION

69. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

70. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Pelvic Mesh Product had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

71. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Product while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Product's high risk of unreasonable, dangerous, adverse side effects.

72. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Product has no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

73. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to

know, that the Pelvic Mesh Product had been insufficiently tested, or had not been tested at all, and that it lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

74. As a proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V
BREACH OF EXPRESS WARRANTY

75. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

76. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Product.

77. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Product be used in the manner that Plaintiff in fact used it and Defendants expressly warranted that the product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other pelvic mesh products, and that it was adequately tested and fit for its intended use.

78. At all relevant times, Defendants were aware that consumers, including

1 Plaintiff, would use the Pelvic Mesh Product; which is to say that Plaintiff was a
2 foreseeable user of the Defendants' Pelvic Mesh Product.

3 79. Plaintiff and/or her implanting physicians were at all relevant times in
4 privity with Defendants.
5

6 80. The Defendants' Pelvic Mesh Product was expected to reach and did in fact
7 reach consumers, including Plaintiff and her implanting physicians, without substantial
8 change in the condition in which it was manufactured and sold by Defendants.
9

10 81. Defendants breached various express warranties with respect to the Pelvic
11 Mesh Product including the following particulars:
12

- 13 a) Defendants represented to Plaintiff and her physicians and healthcare
14 providers through its labeling, advertising, marketing materials, detail
15 persons, seminar presentations, publications, notice letters, and regulatory
16 submissions that the Defendants' Pelvic Mesh Product was safe and
17 fraudulently withheld and concealed information about the substantial risks
18 of serious injury associated with using the Pelvic Mesh Product;
19
- 20 b) Defendants represented to Plaintiff and her physicians and healthcare
21 providers that the Defendants' Pelvic Mesh Product was as safe, and/or safer
22 than other alternative procedures and devices and fraudulently concealed
23 information, which demonstrated that the Product was not safer than
24 alternatives available on the market; and
25
- 26 c) Defendants represented to Plaintiff and her physicians and healthcare
27 providers that the Defendants' Pelvic Mesh Product was more efficacious
28 than other alternative medications and fraudulently concealed information,
 regarding the true efficacy of the product.

1 82. In reliance upon Defendants' express warranty, Plaintiff was implanted with
2 the Defendants' Pelvic Mesh Product as prescribed and directed, and therefore, in the
3 foreseeable manner normally intended, recommended, promoted, and marketed by
4 Defendants.
5

6 83. At the time of making such express warranties, Defendants knew or should
7 have known that the Defendants' Pelvic Mesh Product does not conform to these express
8 representations because the Defendants' Pelvic Mesh Product was not safe and had
9 numerous serious side effects, many of which Defendants did not accurately warn about,
10 thus making the Defendants' Pelvic Mesh Product unreasonably unsafe for its intended
11 purpose.
12

13 84. Members of the medical community, including physicians and other
14 healthcare professionals, as well as Plaintiff and the Public relied upon the representations
15 and warranties of Defendants in connection with the use recommendation, description,
16 and/or dispensing of the Defendants' Pelvic Mesh Product.
17

18 85. Defendants breached their express warranties to Plaintiff in that the
19 Defendants' Pelvic Mesh Product was not of merchantable quality, safe and fit for its
20 intended uses, nor was it adequately tested.
21

22 86. As a proximate result of the Defendants' conduct, Plaintiff has been injured,
23 often catastrophically, and sustained severe and permanent pain, suffering, disability,
24 impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic
25 damages.
26

27 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
28 individually, jointly, severally and in the alternative, and request compensatory damages,
punitive damages, together with interest, costs of suit, attorneys' fees, and such further

relief as the Court deems equitable and just.

COUNT VI
BREACH OF IMPLIED WARRANTY

87. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

88. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the Defendants' Pelvic Mesh Product.

89. At all relevant times, Defendants intended that the Defendants' Pelvic Mesh Product be implanted for the purposes and in the manner that Plaintiff or Plaintiff's implanting physicians in fact used it and Defendants impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was not adequately tested.

90. Defendants were aware that consumers, including Plaintiff or Plaintiff's physicians, would implant the Defendants' Pelvic Mesh Product in the manner directed by the instructions for use; which is to say that Plaintiff was a foreseeable user of the Defendants' Pelvic Mesh Product.

91. Plaintiff and/or her physicians were at all relevant times in privity with Defendants.

92. The Defendants' Pelvic Mesh Product was expected to reach and did in fact reach consumers, including Plaintiff or Plaintiff's physicians, without substantial change in the condition in which it was manufactured and sold by Defendants.

93. Defendants breached various implied warranties with respect to the Defendants' Pelvic Mesh Product, including the following particulars:

a) Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Pelvic Mesh Product was

1 safe and fraudulently withheld and concealed information about the
2 substantial risks of serious injury associated with using the Pelvic Mesh
3 Product;

- 4
- 5 b) Defendants represented that the Defendants' Pelvic Mesh Product was safe,
6 and/or safer than other alternative devices or procedures and fraudulently
7 concealed information, which demonstrated that the Defendants' Pelvic
8 Mesh Product was not as safe or safer than alternatives available on the
9 market; and
- 10
- 11 c) Defendants represented that the Defendants' Pelvic Mesh Product was more
12 efficacious than alternative pelvic mesh products and procedures and
13 fraudulently concealed information, regarding the true efficacy of the
14 Defendants' Pelvic Mesh Product.

15 94. In reliance upon Defendants' implied warranty, Plaintiff used the Pelvic
16 Mesh Product as prescribed and in the foreseeable manner normally intended, recommended,
17 promoted, and marketed by Defendants.

18 95. Defendants breached their implied warranty to Plaintiff in that the
19 Defendants' Pelvic Mesh Product was not of merchantable quality, safe and fit for its
20 intended use, or adequately tested.

21 96. As a proximate result of the Defendants' conduct, Plaintiff has been injured,
22 often catastrophically, and sustained severe and permanent pain, suffering, disability,
23 impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic
24 damages.

25 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
26 individually, jointly, severally and in the alternative, and request compensatory damages,

punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII
VIOLATION OF CONSUMER PROTECTION LAWS

97. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

98. Plaintiff purchased and used the Defendants' Pelvic Mesh Product primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the consumer protection laws.

99. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' Pelvic Mesh Product, and would not have incurred related medical costs and injury.

100. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the Pelvic Mesh Product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

101. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

- a) Representing that goods or services has characteristics, ingredients, uses benefits or quantities that they do not have;
 - b) Advertising goods or services with the intent not to sell them as advertised; and,
 - c) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding

102. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and

1 consumers was to create demand for and sell the Defendants' Pelvic Mesh Product. Each
2 aspect of Defendants' conduct combined to artificially create sales of the Defendants'
3 Pelvic Mesh Product.
4

5 103. Had Defendants not engaged in the deceptive conduct described above,
6 Plaintiff would not have purchased and/or paid for the Product and would not have incurred
7 related medical costs.

8 104. Defendants' deceptive, unconscionable, or fraudulent representations and
9 material omissions to patients, physicians, and consumers, including Plaintiff, constituted
10 unfair and deceptive acts and trade practices in violation of the state consumer protection
11 laws.
12

13 105. Defendants have engaged in unfair competition or unfair or deceptive acts or
14 trade practices or have made false representations.
15

16 106. Under common law adopted to protect consumers against unfair, deceptive,
17 fraudulent and unconscionable trade and business practices and false advertising,
18 Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to
19 liability under such legislation for unfair, deceptive, fraudulent and unconscionable
20 consumer sales practices.
21

22 107. Defendants violated the laws that were adopted to protect consumers against
23 unfair, deceptive, fraudulent and unconscionable trade and business practices and false
24 advertising, by knowingly and falsely representing that the Defendants' Pelvic Mesh
25 Product was fit to be used for the purpose for which it was intended, when in fact it was
26 defective and dangerous, and by other acts alleged herein. These representations were made
27 in marketing and promotional materials.
28

108. The actions and omissions of Defendants alleged herein are uncured or

incurable deceptive acts under the laws adopted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

109. Defendants had actual knowledge of the defective and dangerous condition
of the Defendants' Pelvic Mesh Product and failed to take any action to cure such defective
and dangerous conditions.

110. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform (if any).

111. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

112. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

113. As a direct and proximate result of Defendants' violations of the states' consumer protection laws, Plaintiff has sustained economic losses and other damages and is entitled to statutory and compensatory, damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT VIII

FRAUD

114. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

115. The Defendants falsely and fraudulently represented and continue to

1 represent to the medical and healthcare community, the Plaintiff, the FDA, and the public
2 that the Products had been tested and were found to be safe and effective.

3 116. The representations made by the Defendants were, in fact, false. When the
4 Defendants made their representations, the Defendants knew and/or had reason to know
5 that those representations were false, and the Defendants willfully, wantonly, and recklessly
6 disregarded the inaccuracies in their representations and the dangers and health risks to
7 users of the Products.

8 117. These representations were made by the Defendants with the intent of
9 defrauding and deceiving the medical community, the Plaintiff, and the public, and also
10 inducing the medical community, the plaintiff, and the public, to recommend, prescribe,
11 dispense, and purchase the Products for use as a means of treatment for stress urinary
12 incontinence and/or prolapse, all of which evinced a callous, reckless, willful, and depraved
13 indifference to the health, safety, and welfare of the Plaintiff.

14 118. In representations to the Plaintiff and/or to Plaintiffs healthcare providers,
15 the Defendants fraudulently concealed and intentionally omitted the following material
16 information:

- 21 a) That the Products were not as safe as other products and procedures
22 available to treat incontinence and/or prolapse;
- 23 b) That the risk of adverse events with the Products was higher than with other
24 products and procedures available to treat incontinence and/or prolapse;
- 25 c) The Products were not adequately tested;
- 26 d) That the limited clinical testing revealed the Products had a higher risk of
27 adverse effects, in addition to, and above and beyond those associated with
28 other products and procedures available to treat incontinence and/or
 prolapse;
- e) That the Defendants deliberately failed to follow up on the adverse results
 from clinical studies and formal and informal reports from physicians and
 other healthcare providers and buried and/or misrepresented those findings;

- f) That the Defendants were aware of dangers in the Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;
 - g) That the Products were defective, and that they caused dangerous and adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;
 - h) That patients needed to be monitored more regularly than usual while using the Products and that in the event the products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly;
 - i) That the Products were manufactured negligently;
 - j) That the Products were manufactured defectively; and
 - k) That the Products were designed negligently, and designed defectively.

119. The Defendants were under a duty to disclose to the Plaintiff and her physicians, the defective nature of the Products, including, but not limited to, the heightened risks of erosion, failure, and permanent injury.

120. The Defendants had sole access to material facts concerning the defective nature of the Products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Products.

121. The Defendants' concealment and omissions of material fact concerning the safety of the Products were made purposefully, willfully, wantonly, and/or recklessly to mislead, to cause the Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Products; and/or to mislead the Plaintiff into reliance and cause the Plaintiff to use Products.

122. At the time these representations were made by the Defendants, and at the time the Plaintiff used the Products, the Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

1 123. The Defendants knew and had reason to know that the Products could and
2 would cause severe and grievous personal injury to the users of the Products, and that they
3 were inherently dangerous in a manner that exceeded any purported, inaccurate, or
4 otherwise downplayed warnings.
5

6 124. In reliance upon these false representations, the Plaintiff was induced to, and
7 did use the Products, thereby sustaining severe and permanent personal injuries and
8 damages.
9

10 125. The Defendants knew or had reason to know that the Plaintiff and her
11 physicians and other healthcare providers had no way to determine the truth behind the
12 Defendants' concealment and omissions, and that these included material omissions of
13 facts surrounding the use of the Products, as described in detail herein.
14

15 126. The Plaintiff reasonably relied on revealed facts which foreseeably and
16 purposefully suppressed and concealed facts that were critical to understanding the real
17 dangers inherent in the use of the Products.
18

19 127. Having knowledge based upon the Defendants' research and testing, or lack
20 thereof, the Defendants blatantly and intentionally distributed false information, including
21 but not limited to assuring the Plaintiff, the public, and Plaintiffs healthcare providers and
22 physicians, that the Products were safe for use as a means of providing relief from stress
23 urinary incontinence and/or prolapse and were as safe or safer than other products and/or
24 procedures available and on the market. As a result of the Defendants' research and testing,
25 or lack thereof, the Defendants intentionally omitted, concealed and suppressed certain
26 results of testing and research to healthcare professionals, the Plaintiff, and the public at
27 large.
28

128. The Defendants had a duty when disseminating information to the public to

1 disseminate truthful information; and a parallel duty not to deceive the public, the Plaintiff,
2 Plaintiffs healthcare providers, or the FDA.

3 129. The information distributed to the public, the medical community, the FDA,
4 and the Plaintiff, by the Defendants included, but was not limited to websites, information
5 presented at medical and professional meetings, information disseminated by sales
6 representatives to physicians and other medical care providers, reports, press releases,
7 advertising campaigns, television commercials, print advertisements, billboards and other
8 commercial media containing material representations, which were false and misleading,
9 and contained omissions and concealment of the truth about the dangers of the use of the
10 Products.

13 130. The Defendants intentionally made material misrepresentations to the
14 medical community and public, including the Plaintiff, regarding the safety of the Products,
15 specifically that the Products did not have dangerous and/or serious adverse health safety
16 concerns, and that the Products were as safe or safer than other means of treating stress
17 urinary incontinence and/or prolapse.

19 131. The Defendants intentionally failed to inform the public, including the
20 Plaintiff, of the high failure rate, including erosion, the difficulty or impossibility of
21 removing the mesh, and the risk of permanent injury. The Defendants chose to over-
22 promote the purported safety, efficacy, and benefits of the Products instead.

24 132. The Defendants' intent and purpose in making these misrepresentations was
25 to deceive and defraud the public, the medical community, and the Plaintiff; to gain the
26 confidence of the public, the medical community, and the Plaintiff; to falsely assure them of
27 the quality and fitness for use of the Products; and induce the Plaintiff, the public and the
28 medical community to request, recommend, prescribe, dispense, purchase, and continue to

1 use the Products.

2 133. The Defendants made claims and representations in documents submitted to
3 the FDA and reports to the public and to healthcare professionals and in advertisements that
4 the Products had innovative beneficial properties and did not present serious health risks.
5 These representations, and others made by the Defendants, were false when made and/or
6 were made with the pretense of actual knowledge when such knowledge did not actually
7 exist, and were made recklessly and without regard to the true facts.

8 134. These representations, and others made by the Defendants, were made with
9 the intention of deceiving and defrauding the Plaintiff, the Plaintiffs healthcare
10 professionals and other members of the healthcare community, and were made in order to
11 induce the Plaintiff, and her respective healthcare professionals, to rely on
12 misrepresentations, and caused the Plaintiff to purchase, rely, use, and request the Products
13 and her healthcare professionals to dispense, recommend, or prescribe the Products.

14 135. The Defendants recklessly and/or intentionally falsely represented the
15 dangerous and serious health and safety concerns inherent in the use of the Products to the
16 public at large, for the purpose of influencing the sales of products known to be dangerous
17 and defective, and/or not as safe as other alternatives.

18 136. The Defendants willfully and intentionally failed to disclose the truth, failed
19 to disclose material facts and made false representations, for the purpose of deceiving and
20 lulling the Plaintiff, as well as her healthcare professionals, into a false sense of security, so
21 that the Plaintiff and her healthcare providers would rely on the Defendants' representations,
22 and the Plaintiff would request and purchase the Products, and that their healthcare
23 providers would dispense, prescribe, and recommend the Products.

24 137. The Defendants utilized direct to consumer advertising to market, promote,

1 and advertise the Products.

2 138. At the time the representations were made, the Plaintiff and her healthcare
3 providers did not know the truth about the dangers and serious health and/or safety risks
4 inherent in the use of the Products. The Plaintiff did not discover the true facts about the
5 dangers and serious health and/or safety risks, nor did the Plaintiff discover the false
6 representations of the Defendants, nor would the Plaintiff with reasonable diligence have
7 discovered the true facts or the Defendants' misrepresentations.

8 139. Had the Plaintiff known the true facts about the dangers and serious health
9 and/or safety risks of the Products, the Plaintiff would not have purchased, used, or relied
10 on the Products.

11 140. The Defendants' wrongful conduct constitutes fraud and deceit, and was
12 committed and perpetrated willfully, wantonly, and/or purposefully on the Plaintiff.

13 141. As a proximate result of the Defendants' conduct, the Plaintiff has been
14 injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of
15 enjoyment of life, and economic damages.

16 142. The wrongs done by Defendants were aggravated by the kind of malice,
17 fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for
18 which the law would allow, and which Plaintiff will seek at the appropriate time under
19 governing law for the imposition of exemplary damages, in that Defendants' conduct,
20 including the failure to comply with applicable Federal standards: was specifically intended
21 to cause substantial injury to Plaintiff; or when viewed objectively from Defendants'
22 standpoint at the time of the conduct, involved an extreme degree of risk, considering the
23 probability and magnitude of the potential harm to others, and Defendants were actually,
24 subjectively aware of the risk involved, but nevertheless proceeded with conscious

1 indifference to the rights, safety, or welfare of others; or included a material representation
2 that was false, with Defendants, knowing that it was false or with reckless disregard as to its
3 truth and as a positive assertion, with the intent that the representation is acted on by
4 Plaintiff.
5

6 143. Plaintiff relied on the representation and suffered injury as a proximate result
7 of this reliance.

8 144. Plaintiff therefore will seek to assert claims for exemplary damages at the
9 appropriate time under governing law in an amount within the jurisdictional limits of the
10 Court.
11

12 145. Plaintiff also alleges that the acts and omissions of named Defendants,
13 whether taken singularly or in combination with others, constitute gross negligence that
14 proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary
15 damages in an amount that would punish Defendants for their conduct, and which would
16 deter other manufacturers from engaging in such misconduct in the future.
17

18 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
19 individually, jointly, severally and in the alternative, and request compensatory damages,
20 together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems
21 equitable and just.
22

COUNT IX
UNJUST ENRICHMENT

23 146. Plaintiff realleges and incorporates by reference every allegation of this
24 Complaint as if each were set forth fully and completely herein.
25
26

27 147. Defendants are and at all times were the manufacturers, sellers, and/or
28 suppliers of the Defendants' Pelvic Mesh Product.

148. Plaintiff paid for the Defendants' Pelvic Mesh Product for the purpose of

1 treatment of stress urinary incontinence and/or pelvic organ prolapse or other similar
2 condition.

3 149. Defendants have accepted payment by Plaintiff and others on Plaintiff's
4 behalf for the purchase of the Defendants' Pelvic Mesh Product.

5 150. Plaintiff has not received the safe and effective medical device for which she
6 paid.

7 151. It would be inequitable for Defendants to keep this money since Plaintiff did
8 not in fact receive a safe and effective medical device.

9 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
10 individually, jointly, severally and in the alternative, and requests compensatory damages,
11 together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems
12 equitable and just.

13
14 **COUNT X**
GROSS NEGLIGENCE

15 152. Plaintiff realleges and incorporates by reference every allegation of this
16 Complaint as if each were set forth fully and completely herein.

17 153. The wrongs done by Defendants were aggravated by the kind of malice,
18 fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for
19 which the law would allow, and which Plaintiff will seek at the appropriate time under
20 governing law for the imposition of exemplary damages, in that Defendants' conduct,
21 including the failure to comply with applicable Federal standards: was specifically intended
22 to cause substantial injury to Plaintiff; or when viewed objectively from Defendants'
23 standpoint at the time of the conduct, involved an extreme degree of risk, considering the
24 probability and magnitude of the potential harm to others, and Defendants were actually,
25 subjectively aware of the risk involved, but nevertheless proceeded with conscious

1 indifference to the rights, safety, or welfare of others; or included a material representation
2 that was false, with Defendants, knowing that it was false or with reckless disregard as to its
3 truth and as a positive assertion, with the intent that the representation is acted on by
4 Plaintiff.
5

6 154. Plaintiff relied on the representation and suffered injury as a proximate result
7 of this reliance.

8 155. Plaintiff therefore will seek to assert claims for exemplary damages at the
9 appropriate time under governing law in an amount within the jurisdictional limits of the
10 Court.

12 156. Plaintiff also alleges that the acts and omissions of named Defendants,
13 whether taken singularly or in combination with others, constitute gross negligence that
14 proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary
15 damages in an amount that would punish Defendants for their conduct, and which would
16 deter other manufacturers from engaging in such misconduct in the future.
17

18 WHEREFORE, Plaintiff demands judgment against Defendants, and each of
19 them, individually, jointly, severally and in the alternative, and request compensatory
20 damages, together with interest, costs of suit, attorneys' fees, and such further relief as the
21 Court deems equitable and just.

23 **COUNT XI**
24 **PUNITIVE DAMAGES**

25 157. Plaintiff realleges and incorporates by reference every allegation of this
26 Complaint as if each were set forth fully and completely herein.
27

28 158. At all times relevant hereto, Defendants knew or should have known that the
Defendants' Pelvic Mesh Product was inherently more dangerous with respect to the risks

1 of erosion, failure, pain and suffering, loss of life's enjoyment, remedial surgeries and
2 treatments in an effort to cure the conditions proximately related to the use of the product, as
3 well as other severe and personal injuries which are permanent and lasting in nature.
4

5 159. At all times material hereto, Defendants attempted to misrepresent and did
6 misrepresent facts concerning the safety of the Defendants' Pelvic Mesh Product.
7

8 160. Defendants' misrepresentation included knowingly withholding material
9 information from the medical community and the public, including Plaintiff, concerning the
10 safety and efficacy of the Defendants' Pelvic Mesh Product.
11

12 161. At all times material hereto, Defendants knew and recklessly disregarded the
13 fact that the Defendants' Pelvic Mesh Product causes debilitating and potentially lethal side
14 effects with greater frequency than safer alternative methods products and/or procedures
and/or treatment.
15

16 162. At all times material hereto, Defendants knew and recklessly disregarded the
17 fact that the Defendants' Pelvic Mesh Product causes debilitating and potentially lethal side
18 effects with greater frequency than safer alternative products and/or methods of treatment
19 and recklessly failed to advise the FDA of same.
20

21 163. At all times material hereto, Defendants intentionally misstated and
22 misrepresented data and continue to misrepresent data so as to minimize the risk of injuries
23 caused by the Defendants' Pelvic Mesh Product.
24

25 164. Notwithstanding the foregoing, Defendants continue to aggressively market
the Defendants' Pelvic Mesh Product to consumers, without disclosing the true risk of side
26 effects when there were safer alternatives.
27

28 165. Defendants knew of the Defendants' Pelvic Mesh Product defective and
unreasonably dangerous nature, but continued to manufacture, produce, assemble, market,
29

1 distribute, and sell the Defendants' Pelvic Mesh Product so as to maximize sales and profits
2 at the expense of the health and safety of the Public, including Plaintiff, in conscious and/or
3 negligent disregard of the foreseeable harm caused by the Defendants' Pelvic Mesh Product.
4

5 166. Defendants continue to intentionally conceal and/or recklessly and/or grossly
6 negligently fail to disclose to the public, including Plaintiff, the serious side effects of the
7 Defendants' Pelvic Mesh Product in order to ensure continued and increased sales.

8 167. Defendants' intentionally reckless and/or grossly negligent failure to
9 disclose information deprived Plaintiff of necessary information to enable her to weigh the
10 true risks of using the Defendants' Pelvic Mesh Product against her benefit.
11

12 168. As a direct and proximate result of the foregoing acts and omissions,
13 Plaintiff has required and will require health care and services, and has incurred medical,
14 health care, incidental, and related expenses. Plaintiff is informed and believes and further
15 alleges that Plaintiff will in the future be required to obtain further medical care and/or
16 hospital care and medical services.
17

18 169. Defendants have engaged in conduct entitling Plaintiff to an award of
19 punitive damages pursuant Common Law principles.
20

21 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
22 individually, jointly, severally and in the alternative, and request compensatory damages,
23 together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems
24 equitable and just.
25

PRAYER FOR RELIEF

26 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
27 individually, jointly and severally and requests compensatory damages, together with
28 interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and

proper as well as:

- A. All general, statutory, and compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all injuries and damages, both past and present;
- B. All special and economic damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, pain and suffering;
- C. Attorneys' fees, expenses, and costs of this action;
- D. Double or triple damages as allowed by law;
- E. Punitive and/or exemplary damages;
- F. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and
- G. Such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated this 17th day of July 2020.

Respectfully Submitted,

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